THIS OPINION WAS NOT WRITTEN FOR PUBLICATION
The opinion in support of the decision being entered today
(1) was not written for publication in a law journal and
(2) is not binding precedent of the Board. Paper No. 69

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

MARK D. COCHRAN and DAVID E. JUNKER

Junior Party,

v.

PAULUS J. A. SONDERMEIJER, JOHANNES A. J. CLAESSENS,
and ALBERT P. A. MOCKETT

Senior Party.

Patent Interference No. 103,613

HEARD: November 17, 1999

Before CAROFF and DOWNEY and LORIN, Administrative Patent Judges.

CAROFF, Administrative Patent Judge.

1 Application 08/322,726, filed 10/13/94. Accorded benefit of serial no. 08/055,924, filed 04/30/93, now abandoned; and 07/898,087, filed 06/12/92, now abandoned. Assigned to Syntro Corporation which is a wholly owned subsidiary of Mallinckrodt Veterinary, Inc., which is a wholly owned subsidiary of Mallinckrodt Inc.

2 Application 07/621,193, filed 11/30/90, now U.S. Patent No. 5,187,087, granted 02/16/93. Assigned to Akzo Nobel, N.V.

FINAL DECISION Under 37 CFR § 1.658(a)1

This interference involves an application of the junior party, Cochran et al. (Cochran), and a patent of the senior party, Sondermeijer et al. (Sondermeijer).

According to the record before us, the involved Cochran application is assigned to Syntro Corporation which is a wholly owned subsidiary of Mallinckrodt Veterinary, Inc., which in turn is a wholly owned subsidiary of Mallinckrodt, Inc. (Paper No. 7). According to the Cochran Brief, page i (CB-i), the assets of Mallinckrodt Veterinary, Inc. have been acquired by affiliates of Schering-Plough Corporation. Further, the involved Sondermeijer patent is assigned to Akzo Nobel, N.V. (Paper No. 6).

The subject matter involved in this interference relates to a recombinant Herpesvirus of Turkeys (HVT) which includes a heterologous nucleic acid sequence, i.e., a foreign gene, introduced in an insertion region of the HVT genome. According to the specifications of Cochran and Sondermeijer, the subject recombinant virus may be used to prepare a vaccine against certain infectious diseases of poultry such as Marek's disease (MD) which is caused by Marek's disease virus (MDV).

The recombinant HVT is more particularly defined by the sole count of this interference as follows:

Count 13

A recombinant Herpesvirus of Turkeys (HVT) comprising either:

(a) a heterologous nucleic acid sequence, said nucleic acid sequence being introduced in an insertion region of the HVT genome which comprises the genomic region from the end of ORF-1 through ORF-5 located within a DNA fragment of the HVT genome having a restriction map defined by Fig. 1 of patent 5,187,087;

or,

(b) a foreign gene, said foreign gene being inserted into the StuI site within the US2 gene of the HVT.

The claims of the parties which correspond to this count are:

Cochran et al.:	Claims 1, 4, and 124
Sondermeijer et al.:	Claims 1-19

3 It is undisputed that Cochran uses the term US2 gene to refer to the same HVT genomic region which Sondermeijer refers to as ORF-4. In this regard, see the examiner's § 1.609(b) statement (page 3) which was forwarded along with her initial memorandum (form PTO-850), and the involved Cochran application (Paper No. 24, pages 3-4) wherein Cochran notes that "US2 gene" and "ORF-4" are merely two different names given to the same genomic region of the HVT virus.

4 We note that Cochran filed an unauthorized amendment on November 24, 1998 during the pendency of this interference in an attempt to cancel claim 12 (Cochran application: Paper No. 36). Pursuant to 37 CFR § 1.615(a), the amendment has not and will not be entered.

Accordingly, Cochran claim 12 remains pending and at issue in this interference.

A combined Decision on Motions and Order to Show Cause (Paper No. 37) was rendered on October 30, 1998. In that decision, the Administrative Patent Judge (APJ) found with respect to Sondermeijer motion 4 that all of Cochran's involved claims are unpatentable under 35 U.S.C. § 102 (b)/§ 103 based upon the disclosure of either the Australian or Canadian counterpart of the involved Sondermeijer patent, taken alone or in combination with an article by Ross et al.

Accordingly, the fundamental issue presented for decision is whether the APJ properly granted Sondermeijer's motion for judgment (motion 4) based on a sound and thorough evaluation of the evidence of record and the positions of each party.

Each of the parties has presented an evidentiary record, submitted exhibits, filed briefs and appeared, through counsel, at final hearing.

No issue of interference-in-fact has been directly raised in this proceeding.

Preliminary Matter

Initially, we turn to Sondermeijer's motion under 37 CFR § 1.656(h) to suppress evidence (Paper No. 60) to which Cochran has filed an opposition (Paper No. 63). The motion seeks suppression of documents including, inter alia, Declaration of

Martha Wild, Declaration of Janis McMillen and an article by Zelnik et al., all having been previously submitted by Cochran as attachments to its response (Paper No. 38) filed November 24, 1998 to the Order to Show Cause of October 30, 1998.

Sondermeijer's motion to suppress is hereby Granted. In an Order dated December 3, 1998 (Paper No. 39), the APJ gave numerous reasons for refusing to consider the disputed documents; among those reasons being: (a) a failure to file a proper § 1.635 motion to take additional testimony in compliance with the requirements of 37 CFR § 1.637(b); (b) a failure to show good cause why the requested testimony could not have been timely and **appropriately** presented along with Cochran's opposition to motion 4; and (c) a failure to adequately address the issue of whether new arguments and evidence presented by Sondermeijer by way of reply to Cochran's opposition to motion 4 were appropriate as being directed to new points raised in the Cochran opposition. It is our opinion that each of these reasons provides a sound and valid basis for refusing to consider the disputed documents, and Cochran has failed to convince us otherwise.

Accordingly, we agree with the APJ that the documents presented by Cochran for the first time in response to the Order to Show Cause were manifestly belated and, thus, not entitled to

consideration in this interference. In this regard, we note that submission of belated documents in this manner is tantamount to filing "a reply to a reply," which is not authorized by the rules of interference practice.

OPINION

With respect to the patentability issue, Cochran's involved claims in dispute are reproduced below for convenient reference:

Claim 1

A recombinant herpesvirus of turkeys designated S-HVT-045 (ATCC Accession No. VR 2383).

Claim 4

A recombinant herpesvirus of turkeys designated HVT-012 (ATCC Accession No. VR 2382).

Claim 12

A recombinant Herpesvirus of Turkeys (HVT) comprising a foreign gene, said foreign gene being inserted into the StuI site within the US2 gene of the HVT.

According to Cochran's specification, S-HVT-045 of claim 1 represents a species of the recombinant HVT of claim 12 wherein the inserted foreign gene is specifically the gB protein gene of MDV under the control of its endogenous MDV promoter. Additionally, HVT-0121 of claim 4 represents a species of the

5 We presume HVT-012 refers to the same recombinant HVT which is designated as "S-HVT-012" in the specification.

recombinant HVT of claim 12 wherein the inserted foreign gene is a lac Z gene of E. coli which encodes the beta galactosidase protein. A feature common to all of these claims is that the foreign gene is inserted into a StuI restriction enzyme site within the US2 gene (ORF4) of a naturally occurring HVT.

After a thorough evaluation of all the evidence of record in light of the opposing arguments advanced by the parties in their briefs, we are convinced that Sondermeijer established an evidentiary basis for a prima facie case of obviousness in its original motion 4.

To elaborate we note, as pointed out in the Decision on Motions, that there is no dispute that AU-A-67698/90 (the Australian counterpart of the involved Sondermeijer patent) and 2,031,164 (the Canadian counterpart of the involved Sondermeijer patent) constitute prior art, within the context of 35 U.S.C.
102(b), with respect to Cochran's involved claims. There is also no dispute that the disclosures in these two prior art references are essentially identical to the disclosure in the involved Sondermeijer patent.

We take special note of the following excerpts from the Australian reference which we label I-IV:

I.

The prerequisite for a useful recombinant HVT is that the heterologous nucleic acid sequence is incorporated in a permissive position or region of the genomic HVT sequence, i.e. a position or region which can be used for the incorporation of a heterologous sequence without disrupting essential functions of HVT such as those necessary for infection or replication. Such a region is called an insertion-region. [page 4]

II.

The insertion region disclosed herein . . . begins at the end of an open reading frame (ORF-1) . . . Said insertion region of about Skb continues through the ORF's 2, 3, 4 and 5. . . DNA sequences corresponding to the insertionregion outlined above can be applied for the insertion of genes into the HVT genome <u>without disrupting essential functions of the virus.</u> [page 4-5] (underlying added for emphasis)

III.

In another example significant parts of the <u>ORF-4</u> and ORF-5 have been deleted from the HVT genome and replaced by the <u>Bgalactosidase marker gene</u> resulting in recombinant viruses comparable with recombinant HVT viruses comprising an insertion of the marker gene in ORF-2 or ORF-3. [page 5] (underlying added for emphasis)

IV.

The heterologous nucleic acid sequence to be incorporated into the HVT genome according to the present invention can be derived from any source, e.g. viral, prokaryotic, eukaryotic or synthetic. Said nucleic acid sequence can be derived from a pathogen, preferably an avian pathogen, which after insertion into the HVT genome can be applied to induce immunity against disease. Preferably,

> nucleic acid sequences derived from Infectious Bronchitis Virus (IBV), Mare k's Disease Virus MDV , Newcastle Disease Virus (NDV), Infectious Bursal Disease Virus (IBDV), Chicken Aneamia Agent (CAA), Reo Virus, Avian Retro Virus, Fowl Adeno Virus, Turkey Rhinotracheitis Virus, Eimeria species, Salmonella species, Escherichia coli and Mycoplasma gallisepticum are contemplated for incorporation into the insertion-region of the HVT genome. [page 8] (underlying added for emphasis).

In view of the foregoing, the conclusion is inescapable that it would have been prima facie obvious, within the ambit of 35 U.S.C. § 103, to insert a selected foreign gene with an appropriate promoter at any convenient site within the US2 gene (ORF·4) of HVT with the expectation of not disrupting essential viral functions of the recombinant HVT as suggested by the Australian reference (excerpts I and II above). Of course, excerpt III more specifically relates to the recombinant species of Cochran claim 4 (HVT-012); whereas excerpt IV relates to the species of

Cochran claim 1 (S-HVT-045). This conclusion is additionally supported by the examiner's § 1.609(b) statement (page 3), which constitutes the basis of this interference, to the effect that:

> The common invention may be considered as an obvious species within the scope of the genus set forth in patent claim 1, since ORF 4 (US2) is located within the genomic region from the end of ORF-1 through ORF5, and the StuI sitewithin ORF4 is an obvious convenient site for insertion. (underlying added for emphasis)

Also, the examiner reached a similar conclusion in an Office Action dated August 3, 1995 (Paper No. 21) in Cochran's involved application.

The documentary evidence (prior art publications) relied upon by Sondermeijer is of sufficient probative value to establish a r~ ima facie case of obviousness. Thus, the burden of coming forward with evidence of non-obviousness (to rebut the 3prima facie case of obviousness) clearly falls upon Cochran. Cochran has failed to satisfy that burden.

The Cochran opposition to motion 4 alludes on page 16 to nine parameters which are allegedly not discussed in the prior art publications cited by Sondermeijer. However, Cochran failed to explain in its opposition (or in its brief at final hearing) the relevance of these parameters to the issue of obviousness. Certainly, if Cochran believed that these parameters were essential elements for establishing a prima facie case of obviousness, it was incumbent upon Cochran to fully explain their relevance, and to demonstrate by the presentation of credible evidence or sound technical reasoning why those parameters are not taught or suggested by the prior art of record, and would not otherwise have been obvious to those of ordinary skill in the art. Cochran failed to do so. Instead, Cochran merely alluded

to the parameters in question and then lept to the conclusion, without providing any explanation or proof, that Sondermeijer did not make out a Qrima facie case. It appears, therefore, that Cochran would have the APJ, or the Board at final hearing, fill in the gaps and make a case for Cochran. We shall not do so since Cochran, the party in opposition, is charged with that responsibility.

Similarly, the Cochran brief (page 21) states that Sondermeijer's position is necessarily based on three premises, i.e., (1) that all five ORF's of the prior art are equivalent (for purposes of inserting a foreign gene in the HVT genome); (2) that all sites within a given ORF are also equivalent; and (3) that all foreign DNA can be stably inserted and expressed in any one of the available sites. Assuming that these premises reasonably follow from the teachings of the prior art (and we are inclined to agree with this assumption in view of our discussion of the prior art, supra), then it was incumbent upon Cochran to refute these premises by the presentation of rebuttal evidence with its opposition. In this regard, the evidence Cochran would like us to consider, e.g., the Declaration of Martha Wild, was not presented with Cochran's opposition. Instead, that evidence

has been found to be belated and inadmissible, supra, and thus not entitled to consideration.

Finally, we recognize that evidence was presented along with Cochran's opposition for the sole purpose of showing unexpected results by demonstrating the superiority of a vaccine containing S-HVT-045 (Cochran specification: pages 20-21) as compared to a vaccine containing rHVT-MDV (Sondermeijer Declaration: Cochran opposition exhibit 1) [6] That showing was found to be unpersuasive by the APJ in his Decision on Motions for the reasons presented in Sondermeijer's reply (Paper No. 34: pages 13-15). Upon review of all the evidence of record at final hearing, including the deposition testimony of Carla Schrier, we also agree that Cochran's showing is unconvincing essentially for the reasons presented in Sondermeijer's reply brief (page 12-23). Since we are in substantial agreement with Sondermeijer's position on this matter as thoroughly set forth in the reply brief, we adopt that position as our own.

For all of the foregoing reasons, we find that all of Cochran's involved claims are unpatentable for obviousness under 35 U.S.C. § 102 (b)/§ 103.

6 According to the Cochran opposition (page 16), rHVT-MDV contains an insertion of the MDV glycoprotein within the ORF-2 region of the HVT genome.

Judgment

In view of the foregoing, judgment is hereby entered as follows:

Cochran et al. the junior party, is not entitled to a patent containing its claims 1, 4 and 12 corresponding to the count.

On the record before us, Sondermeijer et al., the senior party, is entitled to its patent containing claims 1-19 corresponding to the count.

MARC L. CAROFF Administrative latent Judge	)	
MARY F'. DOWNEY Administrative Patent Judge	)	BOARD OF PATENT APPEALS AND INTERFERENCES
HUBERT C. LORIN Administrative Patent Judge	)	

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